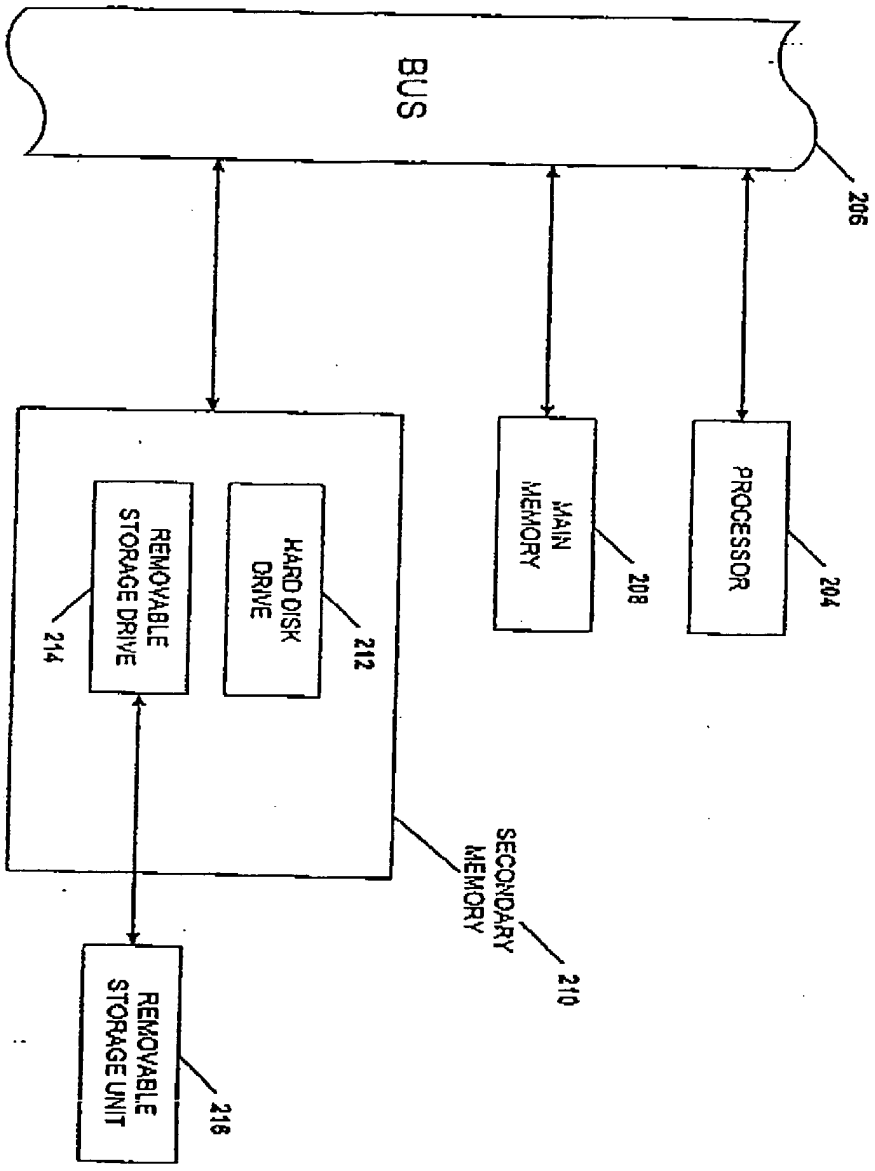


FIG. 1

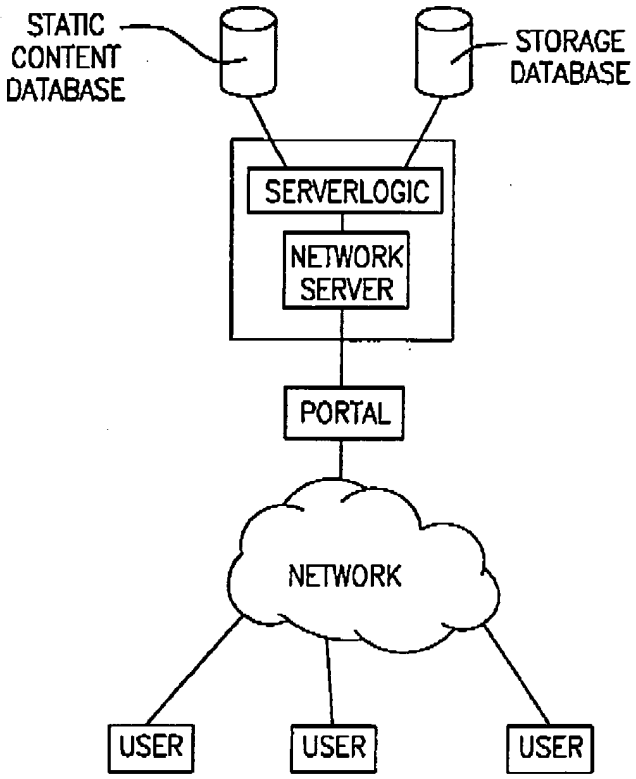


FIG. 2

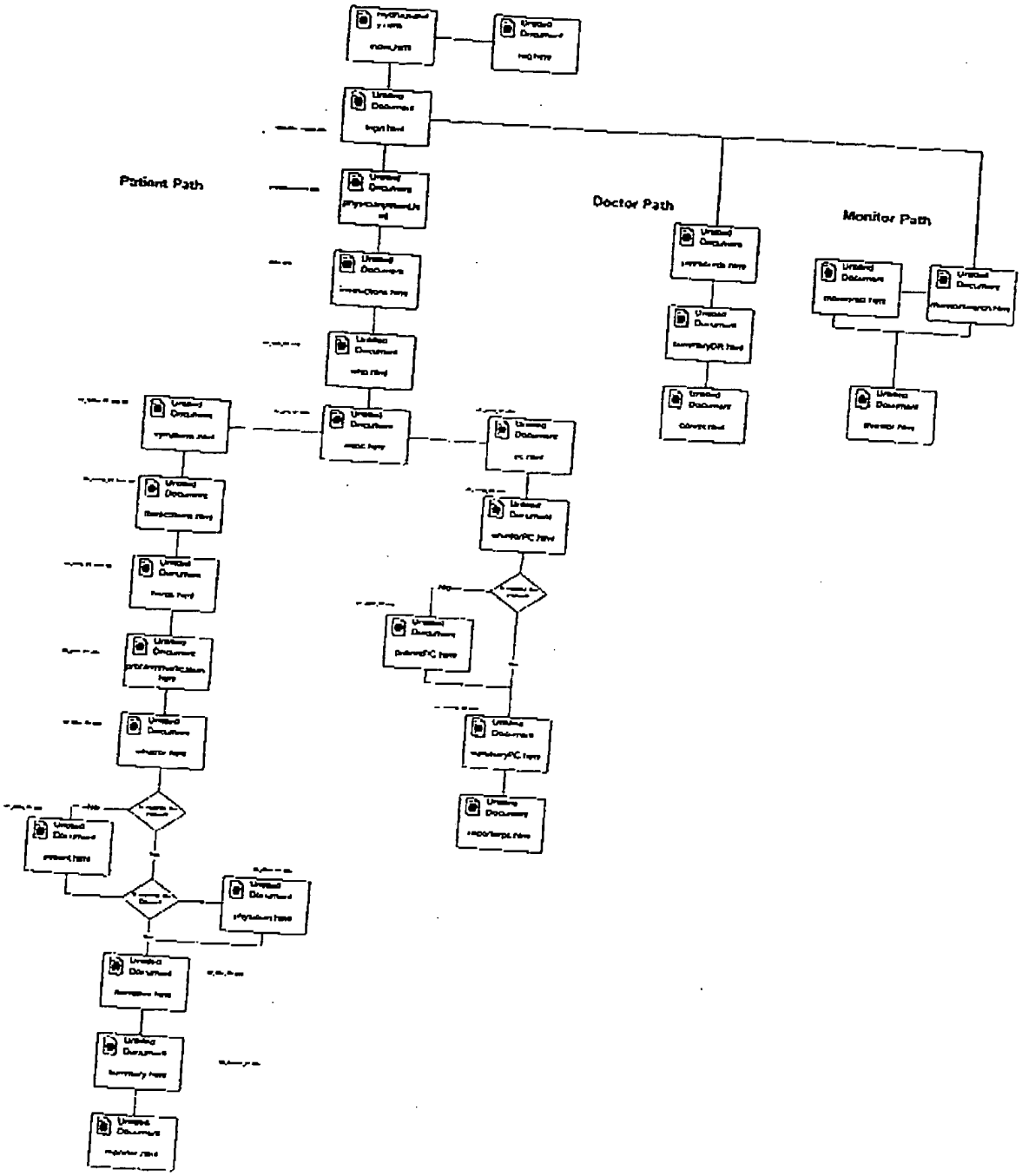


FIG. 3

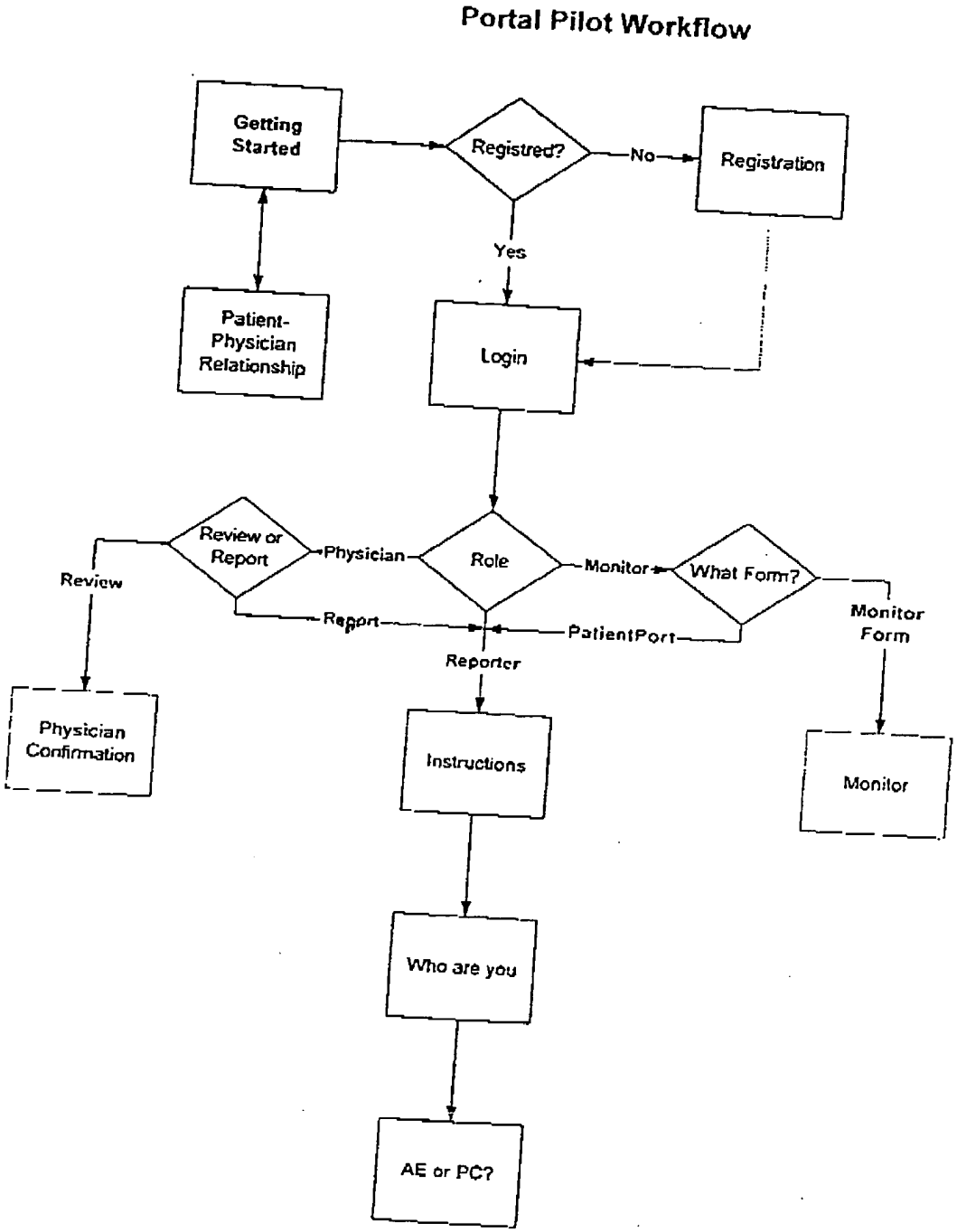


FIG. 3A

AE or PC
Guided Reporting

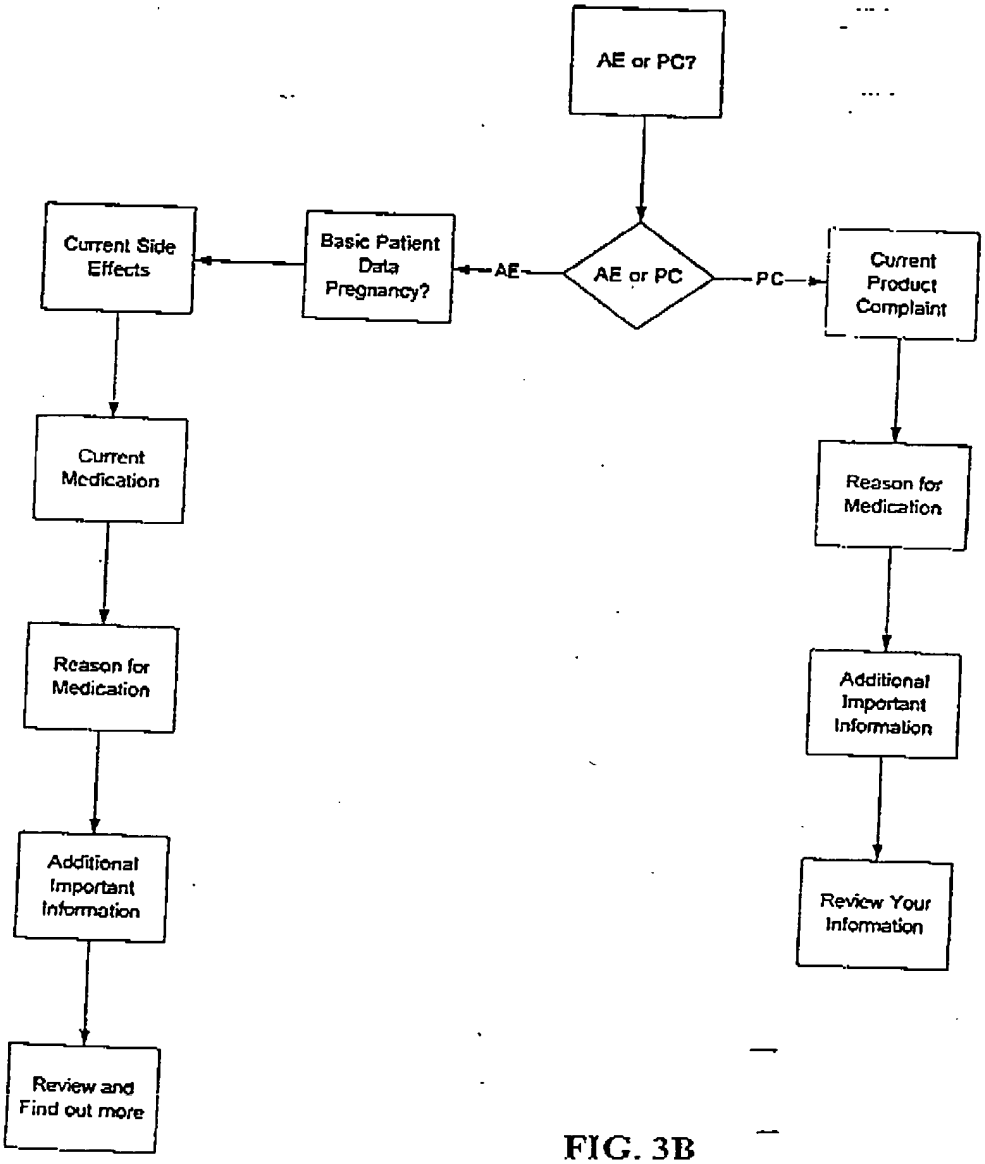


FIG. 3B

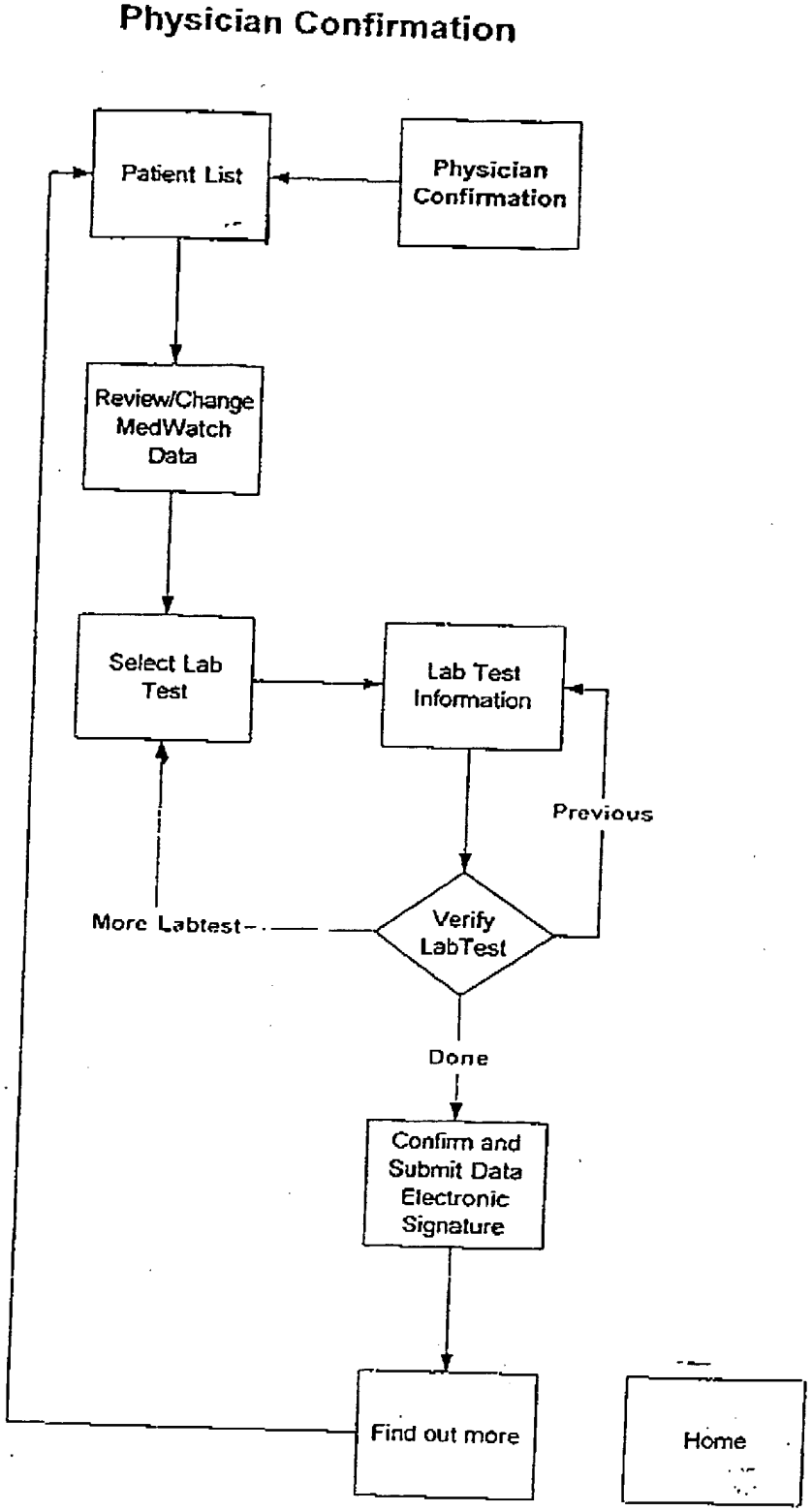


FIG. 3C

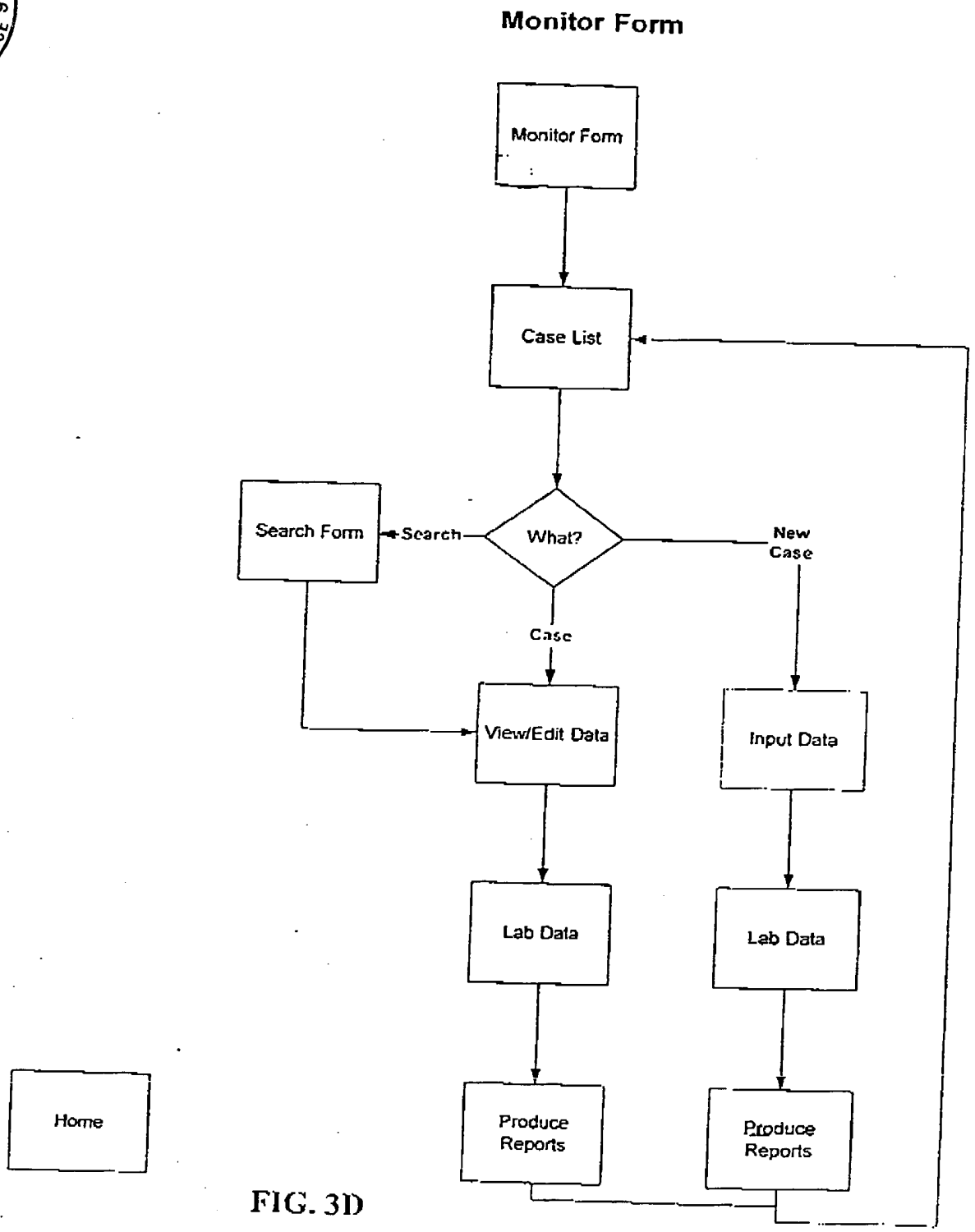


FIG. 3D

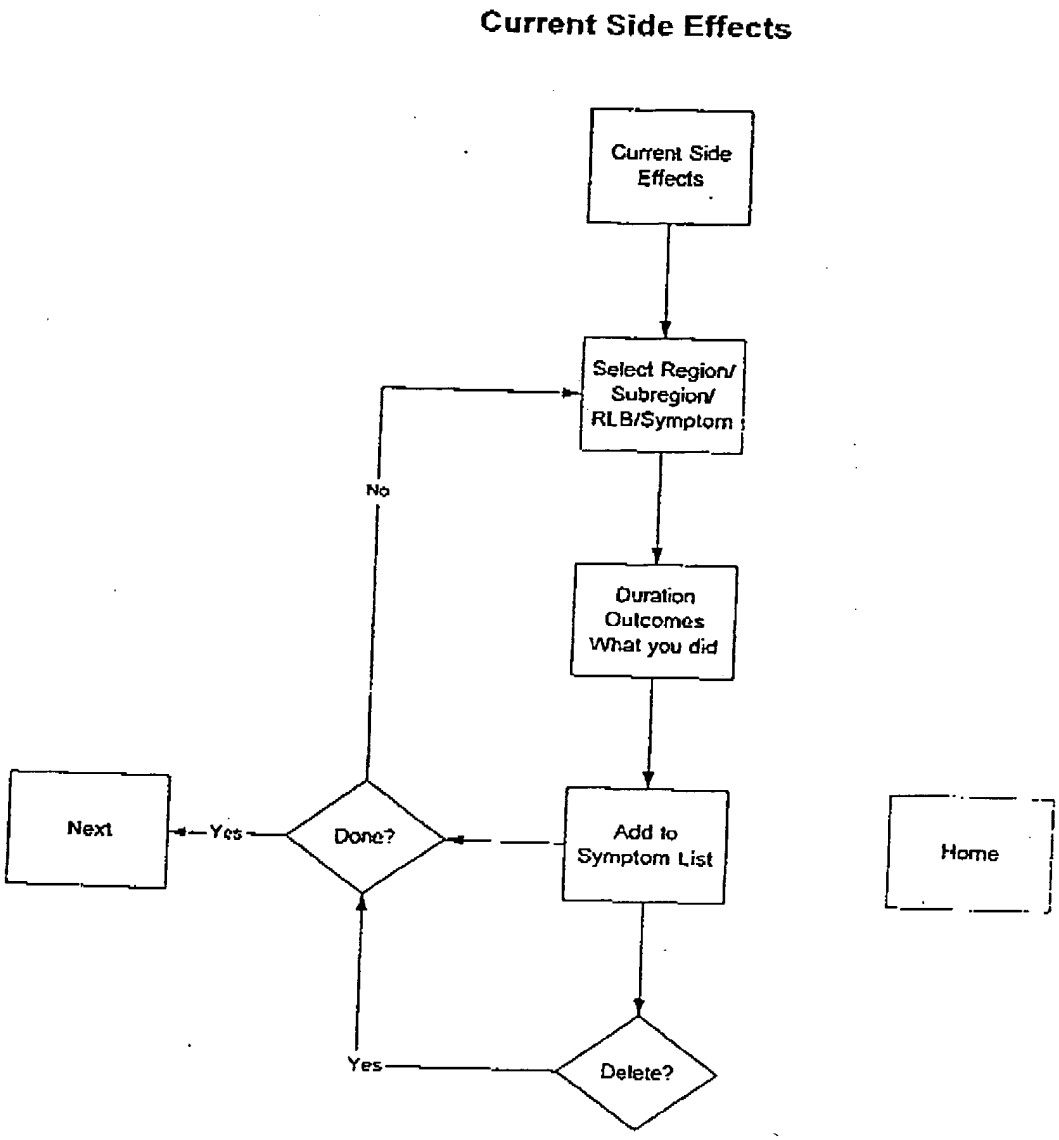


FIG. 3E

Current Medication

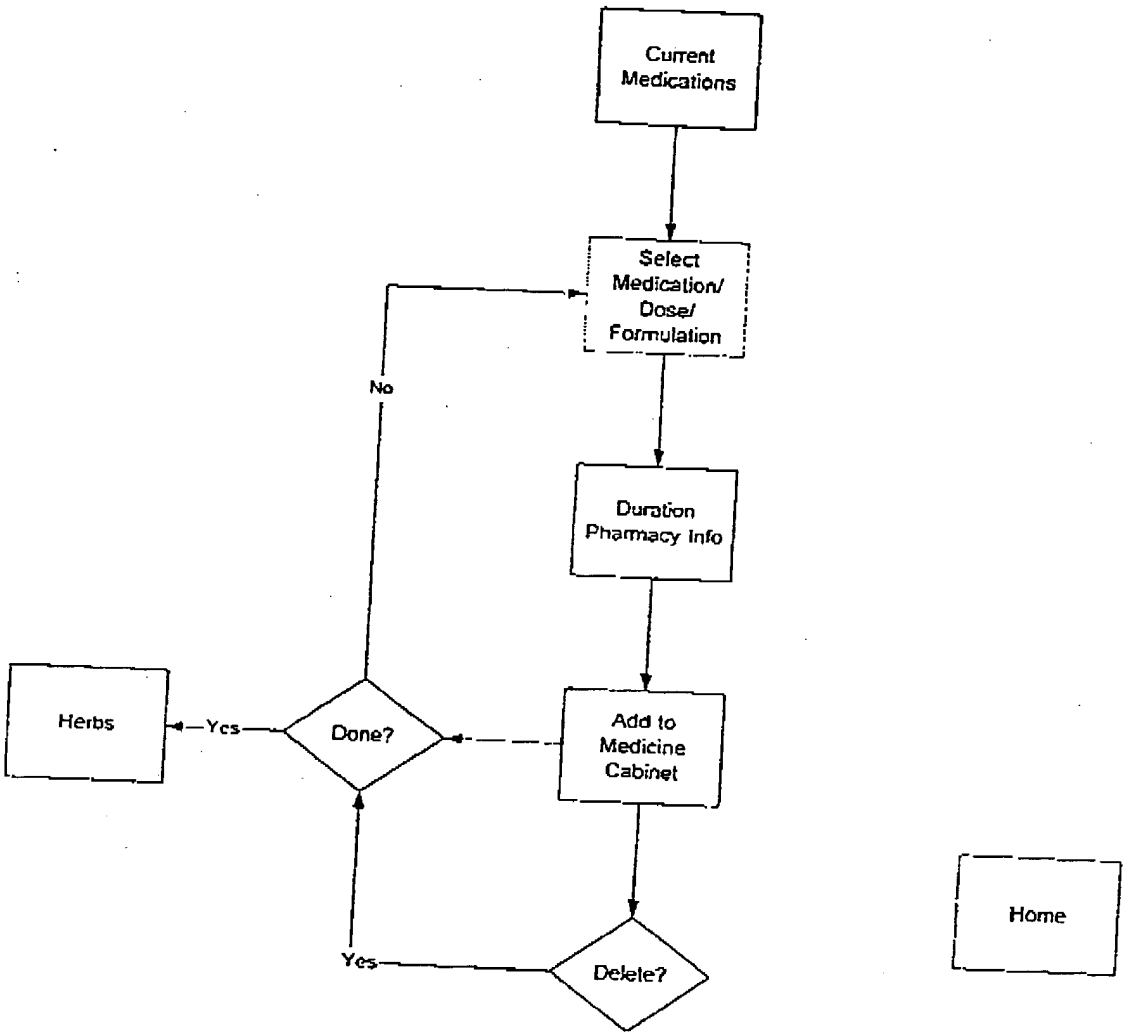


FIG. 3F

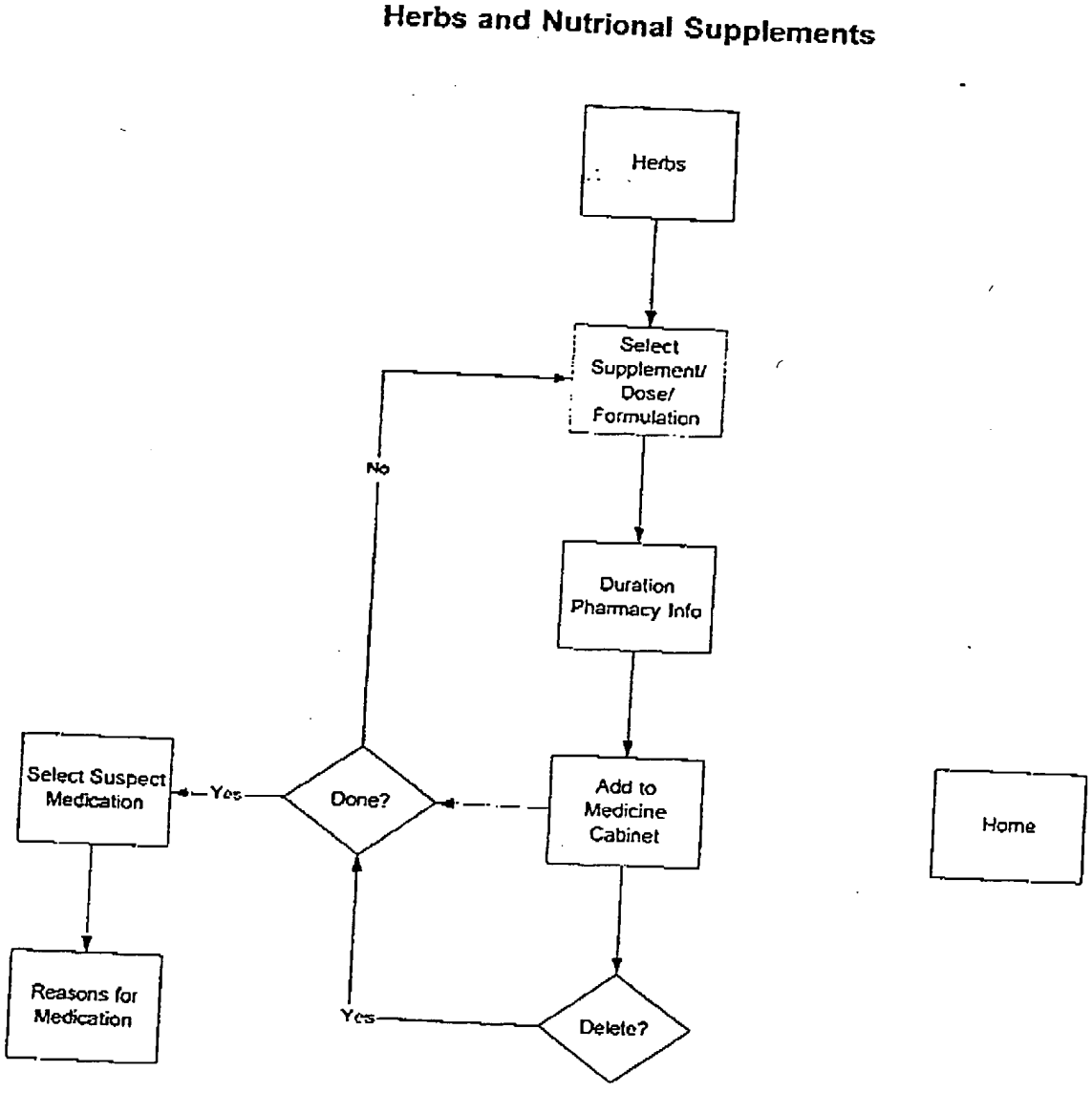


FIG. 3G

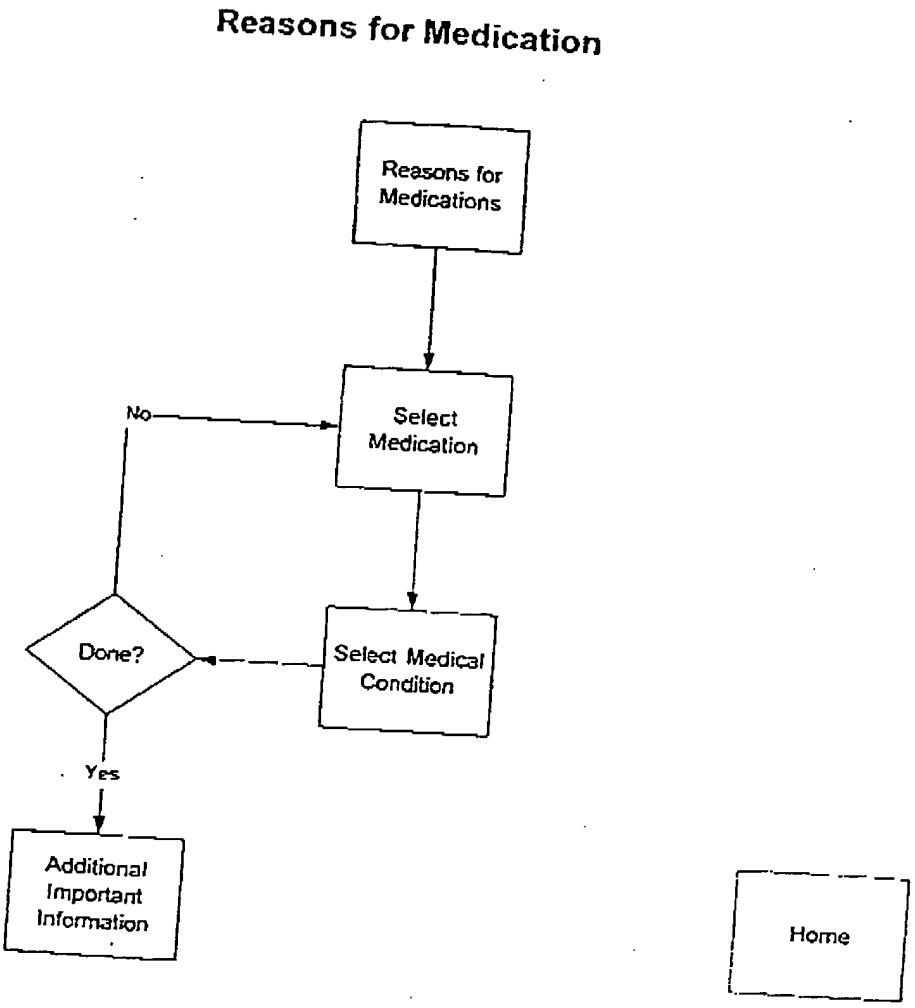


FIG. 3H

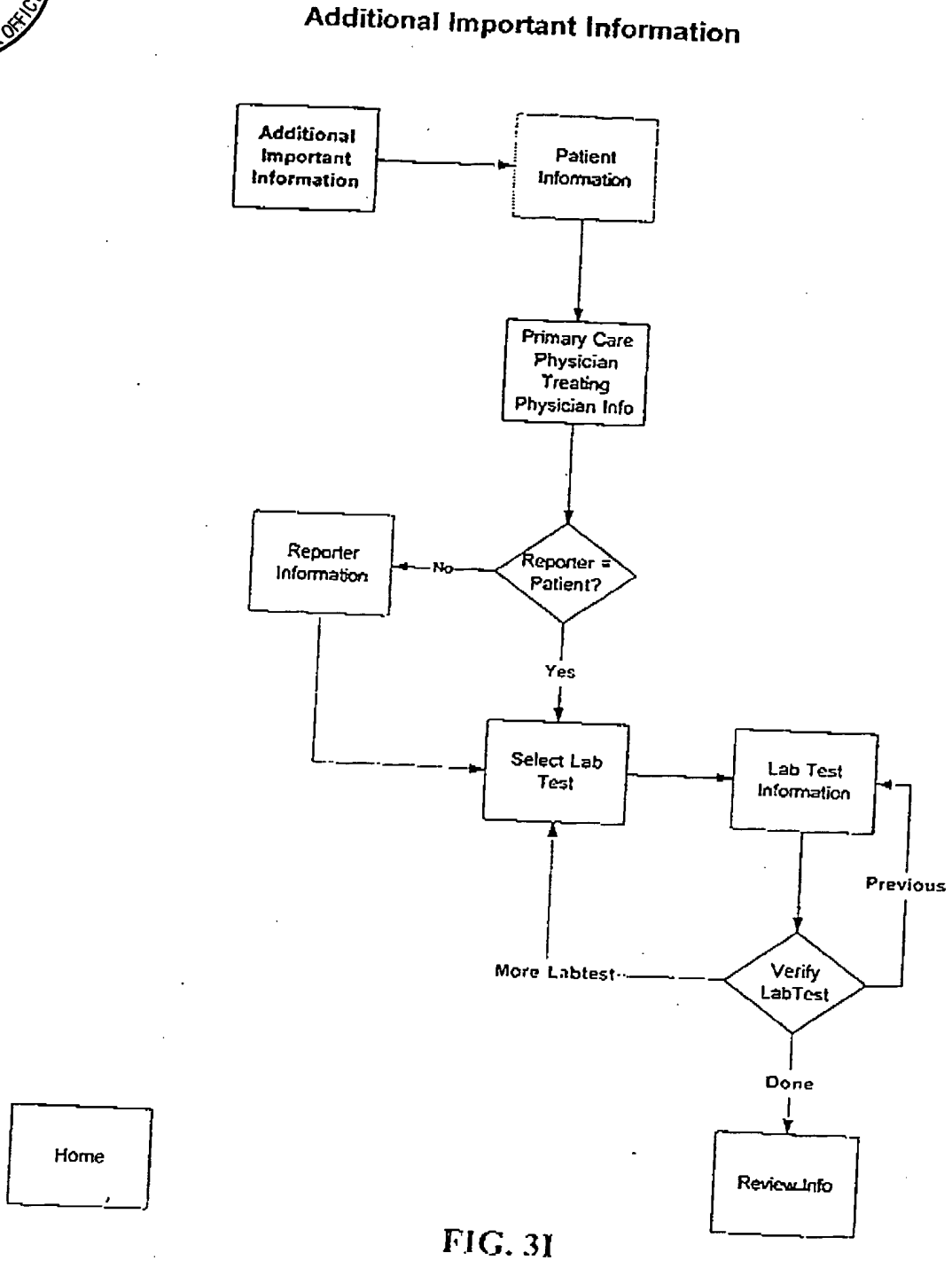


FIG. 31

Review Information and Find out More

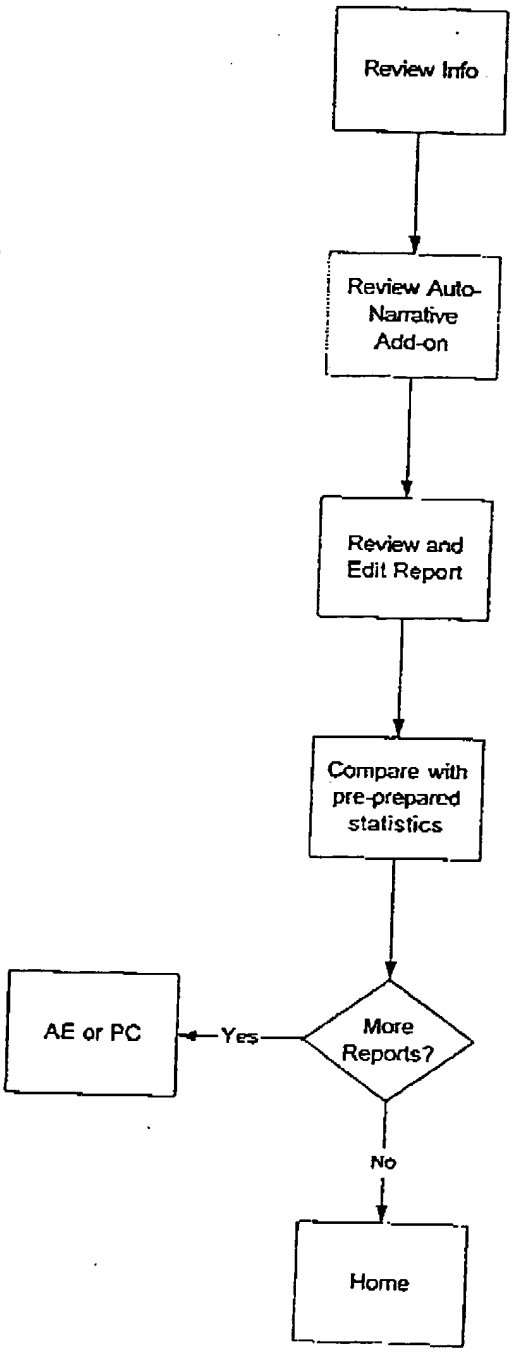


FIG. 3J

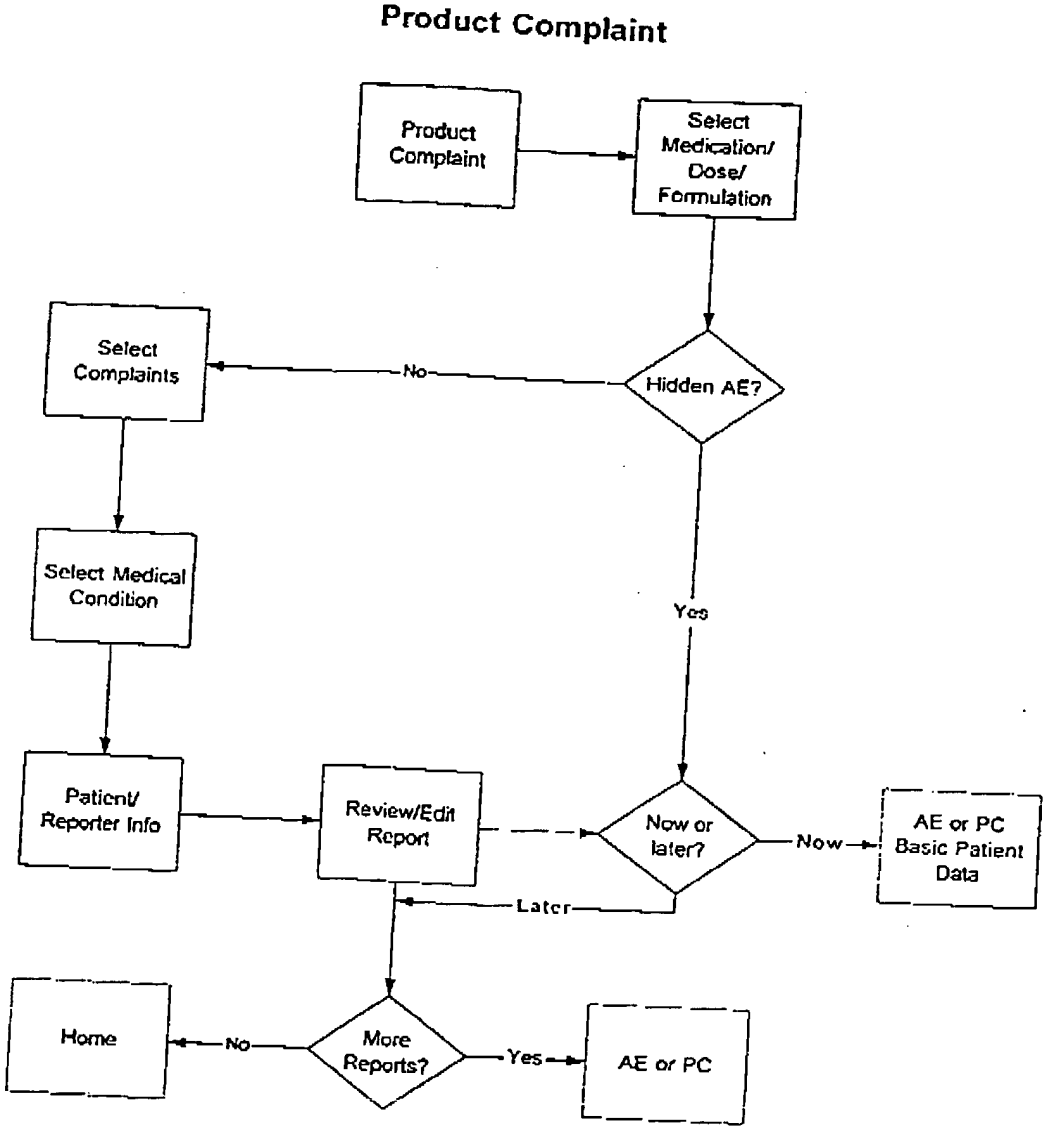
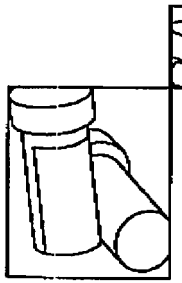


FIG. 3K



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Registration

1 Getting Started
Login/Registration instructions
Who are you
Side Effects and/or Product Complaints

INFORMED CONSENT

IN ORDER TO COMPLETE THE REPORT, WE MAY NEED TO CONTACT YOUR PHYSICIAN. YOUR CONSENT TO CONTACT your physician is called informed consent. Only your physician and you will see the information you provide us.

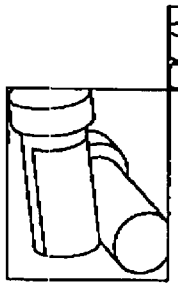
Accept (required to proceed)

This web portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can recreate it: 1)define a secret question (ex: What is my favorite football team) 2)define a secret answer (ex: the SF 49ers). Together these will identify you.

for this pilot, type the 8 digit registration code printed on your trial card. ?

First Name
Last Name
User ID
Password
Password again
Secret Question
Secret Answer
Phone Number
E-mail

FIG. 4



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Welcome to MyDrug Safety

Getting Started

First-time user? Go to our registration page.

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easysteps. At the end, you will receive a summary report for review.

the (?) symbol provides online help. If you would like to read all the instructions for all the screens click here to download.

1 Getting Started
Login/Registration instructions
Who are you
Side Effects and/or Product Complaints

userID and Password (?)

User ID

Password

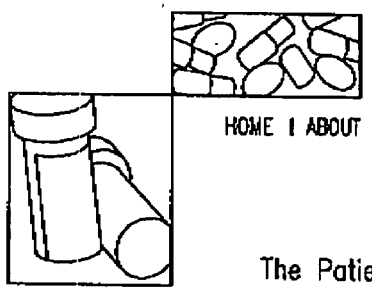
Change your Password?

New Password

Repeat Password

next

FIG. 5



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Patient-Physician Relationship

1 Getting Started
- Login/Registration instructions
- Who are you
- Side Effects and/or Product Complaints

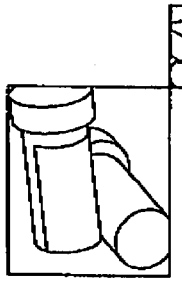
The Patient/Physician Relationship

To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?

Clear | Recover

FIG. 6



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Instructions

1 Getting Started
Login/Registration instructions
Who are you
Side Effects and/or Product Complaints

Easy steps to report a Side Effect or Adverse Event

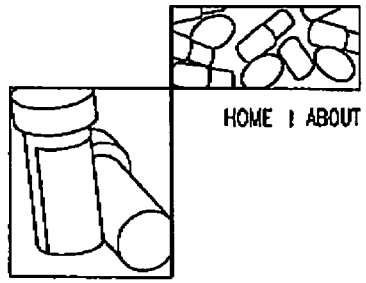
STEP 1: Side effect or you are experiencing
STEP 2: Medications you are taking
STEP 3: Reasons for medication
STEP 4: Additional important information
STEP 5: review your report and find out more

Easy steps to report a Product Complaint

STEP 1: Product complaint
STEP 2: Reason for Medication
STEP 3: Additonal important information
STEP 4: Review your report

Next

FIG. 7



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Who Are You?

?

1 Getting Started
Login/Registration instructions
Who are you
Side Effects and/or Product Complaints

Who Are You?

Family member/spouce

Patient

Patient Caretaker

Pharmaceutical Representative

Treating Physician
Choose One

Someone else? Who?

Other healthcare Professional
Choose One

Previous Next

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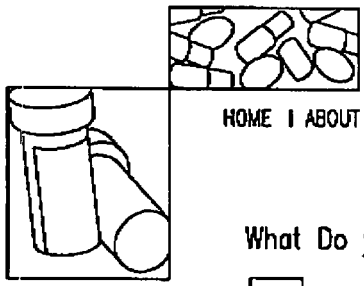
Help

{helpscreens}

FIG. 8



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Adverse Event or Product Complaint?

1 Getting Started
- Login/Registration instructions
- Who are you
- Side Effects and/or Product Complaints

What Do you Want to Rerport? (?)

- [AE] Adverse Reaction or a Sider Effect you are having
- [PC] Complaint about your medication

Family Members Data:

[Male] [Female]

Pregnant ☑ YES

Date of Birth [05-16-70] (mm-dd-yyyy)

or Age [ ] [ ]

Height [5] feet [6] inches
(ex: 5 feet 2 inches)

Weight [110] lbs

[next]

FIG. 9

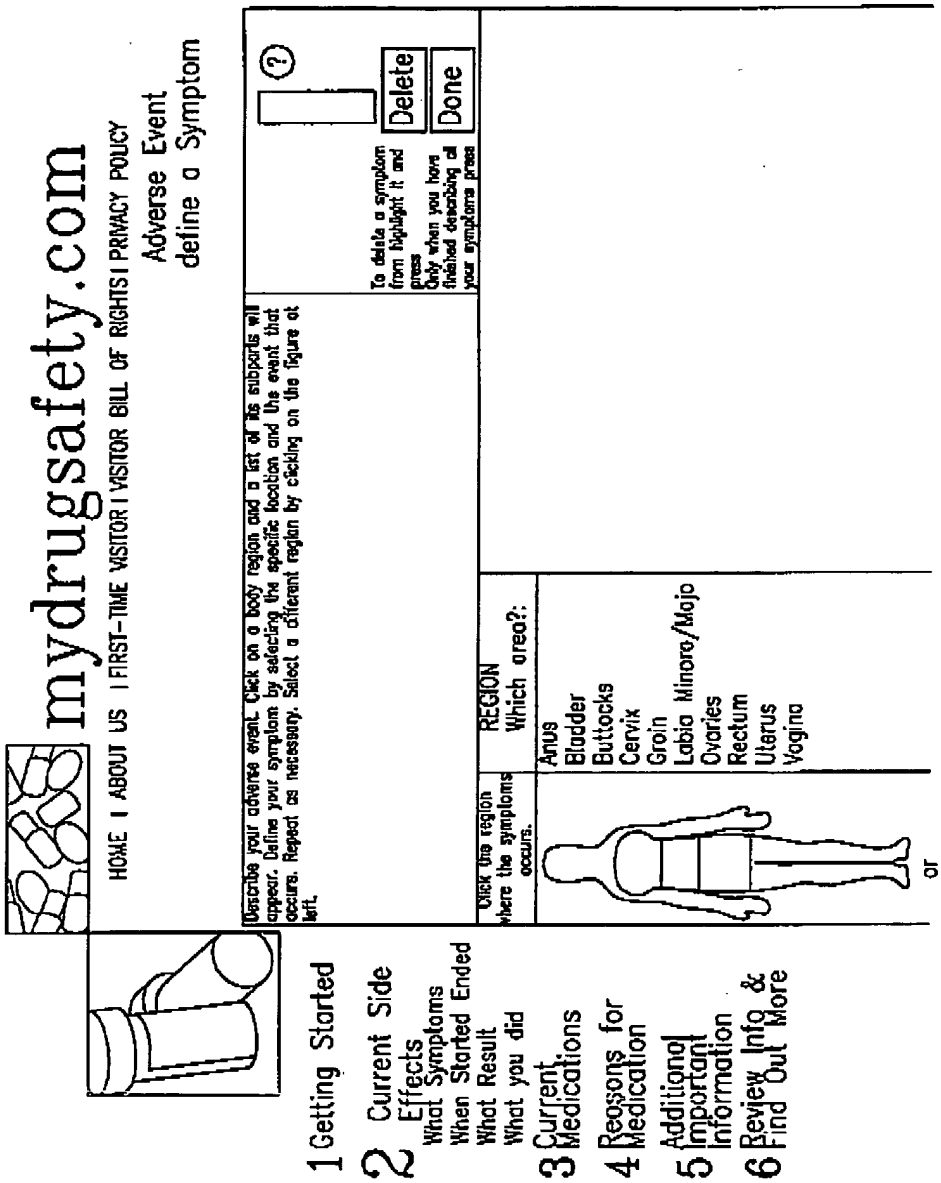


FIG. 10a

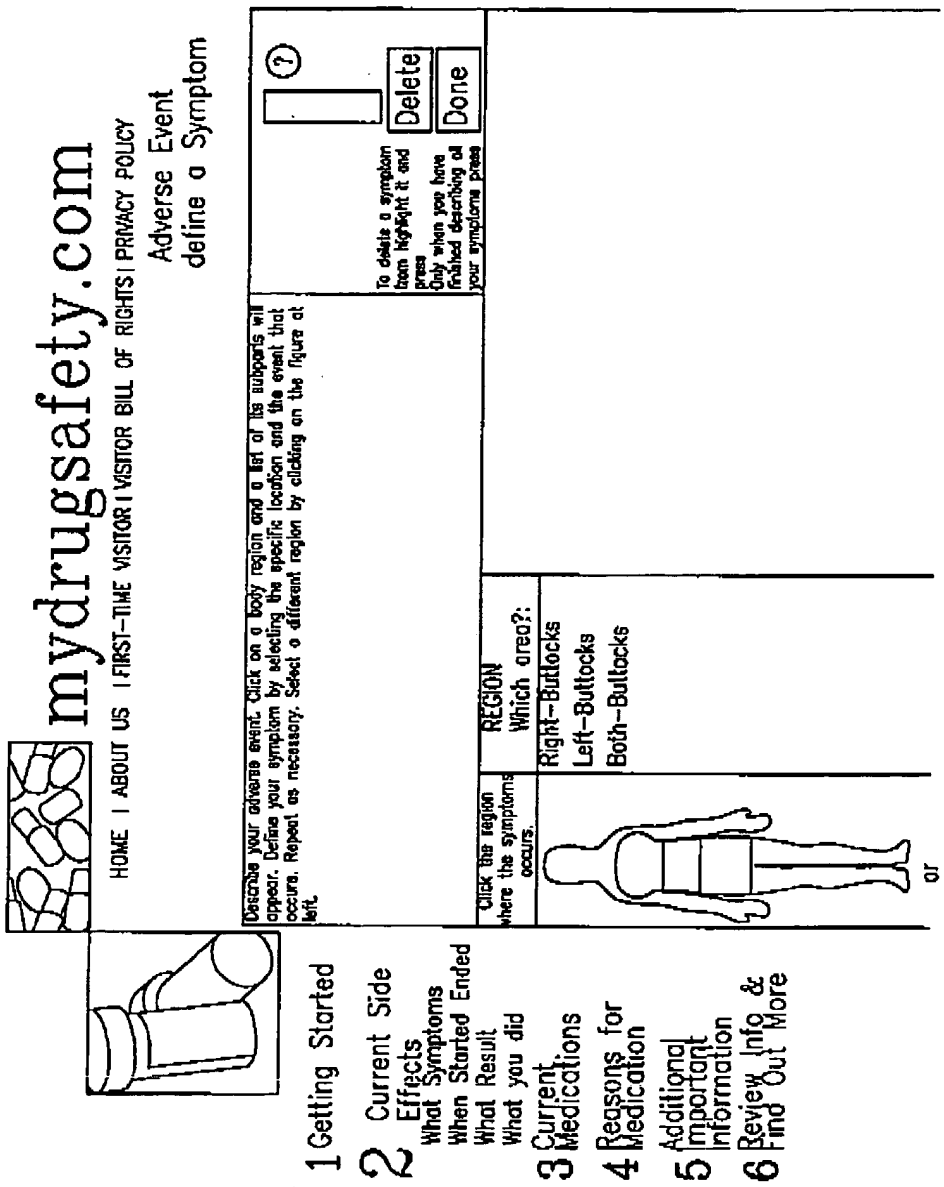


FIG. 10b

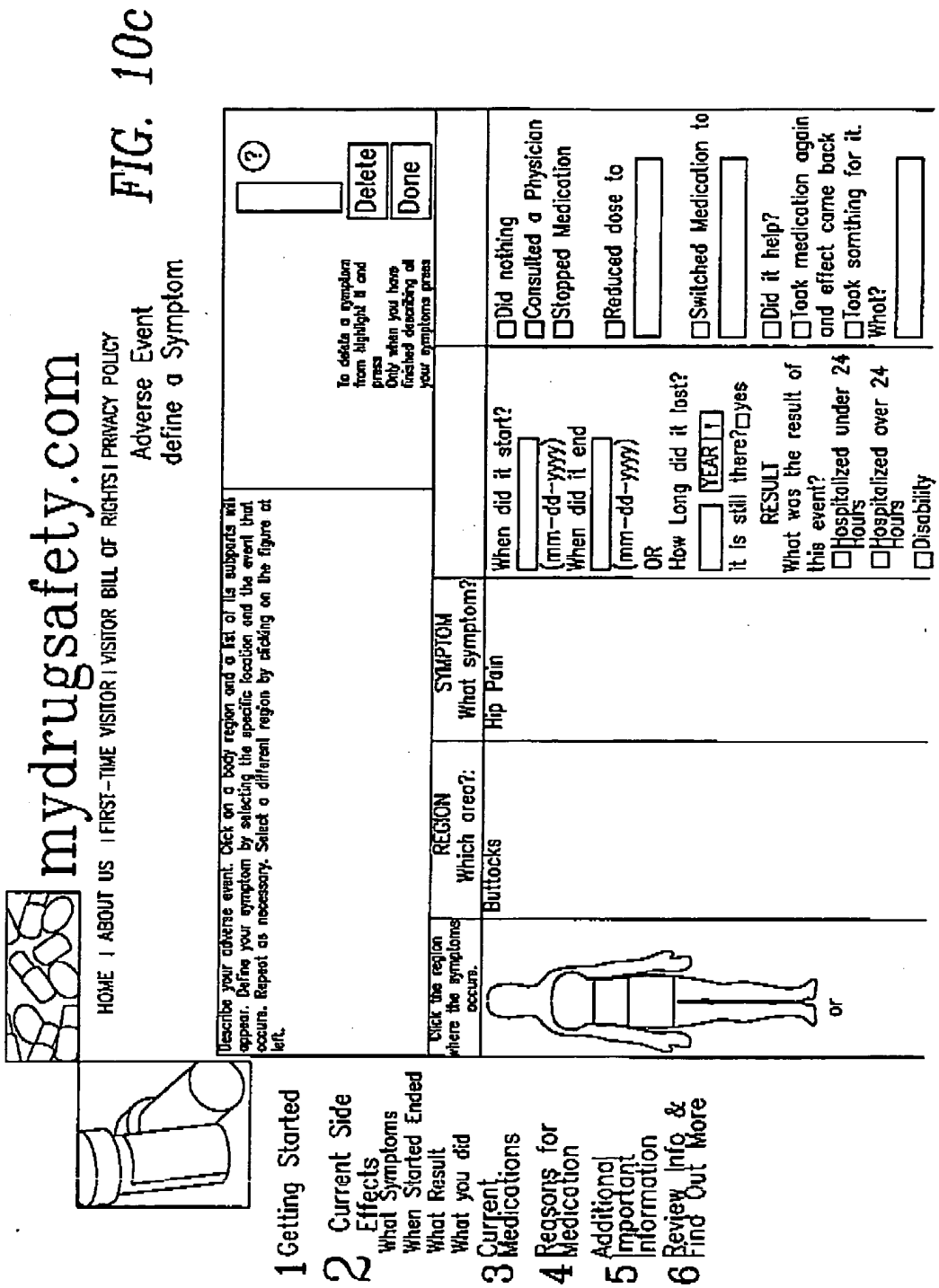


FIG. 10c

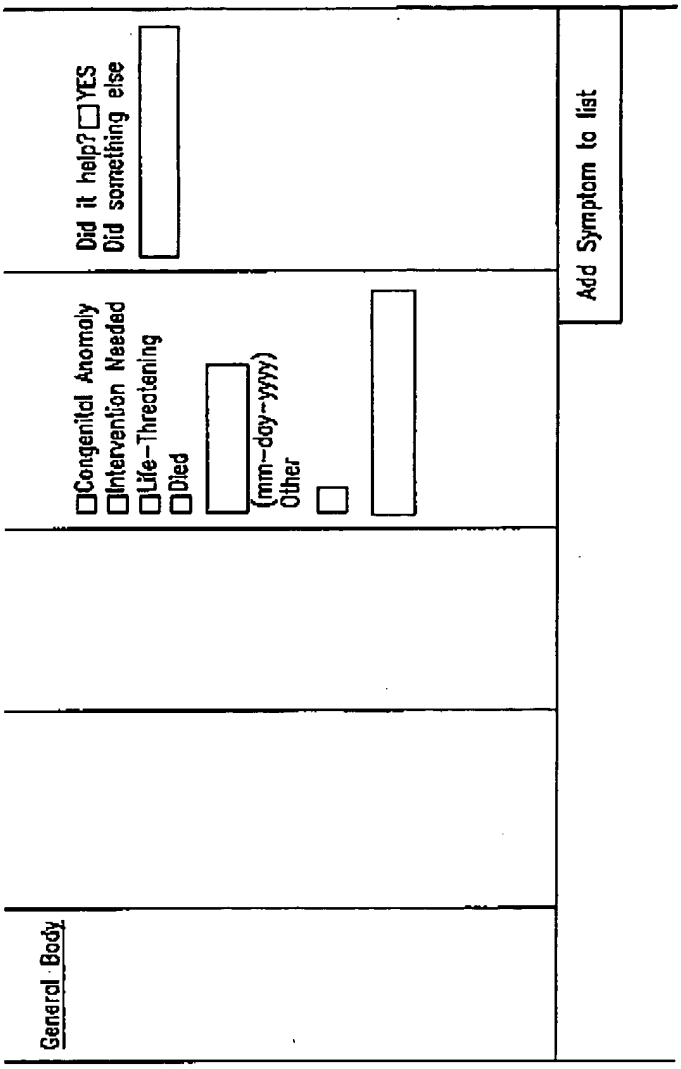


FIG. 10d

FIG. 11

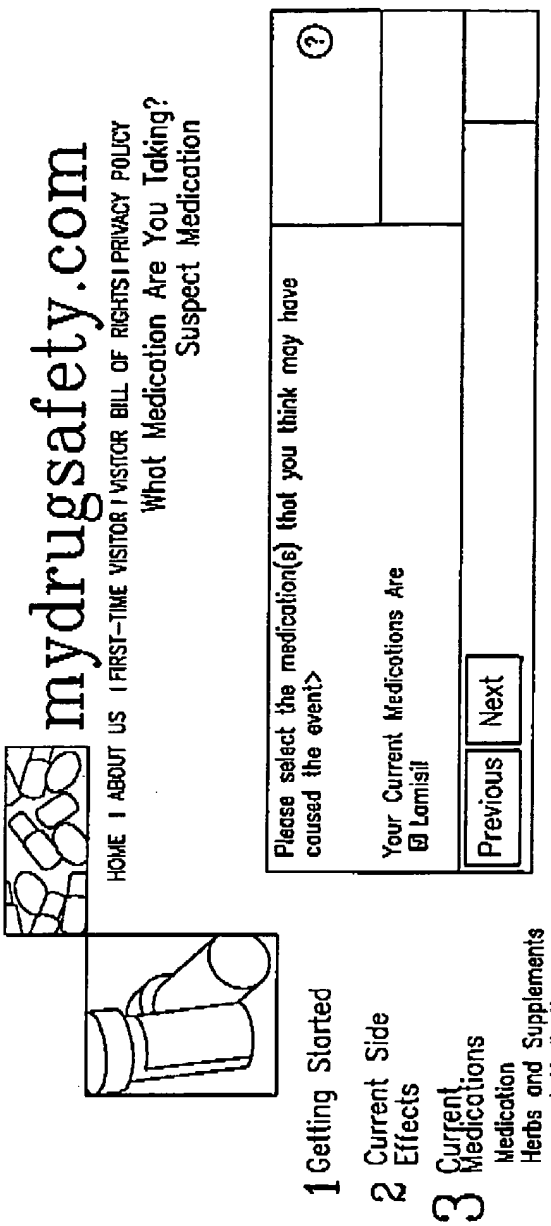
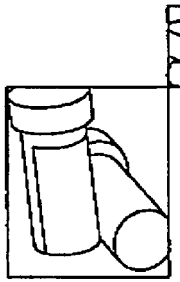


FIG. 12

FIG. 13



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Adverse Event

What Are You Taking Your Medication For?

What condition are you taking your medication for? click on your medication and a list of its associated condition/disease will appear. select the appropriate one. Repeat for each medicine in the list.

Your Medication List				Medical Condition
Medication	Formulation	Dose	Frequency (Times a day)	
Lamisil	Cream	1%	4	Select only one Not on this list?....Enter below

Previous | Next

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Help

{helpscreens}

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FIG. 14A

PatientPort



Adverse Event
Lab Results

Tell us what tests were done.
Click letter to choose from list. ABCDEFGHIJKLMNOPQRSTUVWXYZ ?

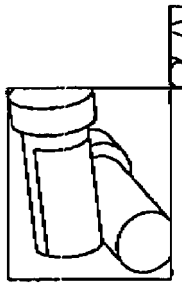
Then Select the appropriate test and method for the specimen, enter results. Standard values for the test will be presented with an indicator for whether the patient values are within range or out of range.

Test	Specimen	Method	Min–Max	test Value Measurement Time & Date	Status of Test
Abumin	Serum	Colimentry	3.5–5.0 g/dl	[ ] g/dl time dd mmm year O Multiple test values at this date?	O
Aldolase				[ ] g/dl time dd mmm year O Multiple test values at this date?	O
Aldosterone				[ ] g/dl time dd mmm year O Multiple test values at this date?	△
Alkaline				[ ] g/dl time dd mmm year O Multiple test values at this date?	△
Phosphatase				[ ] g/dl time dd mmm year O Multiple test values at this date?	O

Next

FIG. 14b

FIG. 15



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Review Your & Who Record
Summary Report
pat1 patlast

Review and Edit your report,

Type over text to edit and only when complete press Report is complete

1 Getting Started
2 Current Side Effects
3 Current Medications
4 Reasons for Medication
5 Additional Important Information
6 Review Info & Find Out More

Review narrative
Review Your Info
Other Simular Reports to the FDA

A. Patient Information

Patient Name: pat1 patlast
Date of Birth: 06-16-70
Age at Event: -30
Gender: ○Male ○Female
Pregnant?: ◉Yes ○No ○Unknown
Weight: 110 Lbs
Height: 5 1 feet 6 1 inches
(ex: 5 feet 2 inches)

A. Adverse Event Results

- ☐ Died On (mm-day-yyyy)
- ☐ Hospitalized Less than 24 Hrs
- ☐ Hospitalized over 24 Hrs
- ☑ Disability
- ☐ Congenitial Anormaly
- ☐ Intervention needed
- ☐ Life threatening
- ☐ Other

Date of Event: (mm-dd-yyyy)
Date of Report: 01-23-2001 (mm-dd-yyyy)

FIG. 16a

Description

Event Abated? ○Yes ○No ○Unknown
Event Reappeared? ○Yes ○No ○Unknown

C. Suspect Medications

Drug Name	Dose	Therapy Dates/Duration	Reason
Lamisil	1%	From 07-01-2000 to 01-01-2001 Duration:1	Disease 2

D. Concomitant Medication

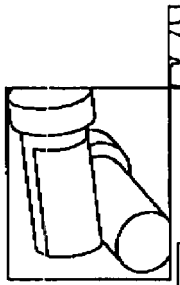
Drug Name	Dose	Therapy Dates/Duration	Reason

Previous Next

Help

{helpscreens}

FIG. 16b



PatientPort

Arzeimittel–Nebenwirkungen definieren Sie Das Symptom

Start

1 Login/Registrierung
Bedienungsanleitung
wer sind Sie?
Arzeimittel–Newbenwirkung oder Beschwerde uber dos Arzeimittel

2 Arzeimittel–Nebenwirkung
Ihre Symptome
Beginn und Ende
Direkte Auswirkungen
Gegenreaktionen

3 Ihre Medikamente
Medikamente
Andere Medikamente
Heilkrauter & Vitamine

4 Weshalb nehmen Sie

Wir bitten Sie, im folgenden Ihre Arzeimittel–Nebenwirkungen zu Beschreiben. klicken Sie bitte eine Korperegion an und es wird eine liste von Sub–Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein symptom aus der prasentierten lisle auswahlen. Durch Anklicken der Figur konnen sie nachher weitere Regionen auswohlen.

Ihre Symptome
Augen, verschwommene Sicht
Augen, verengte Pupillen

Um ein Symptom zu loschen, markieren Sie es bitte und drucken Sie. LOSCHEN

Erst wenn Sie alle Ihre symptome abschliessend beschrieben haben, drucken Sie bitte FERTIG

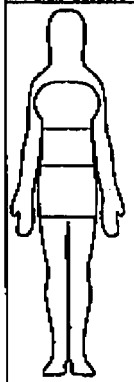
Klicken Sie bitte die Region, in der thr Sympton sich aussert	KOPF Wahlen Sie die Region?:	SYMPTOM Ihr Symptom	DAUER	WAS UNTERNAHMEN SIE DAGEGEN?
	AUGEN	VERENGTE PUPILLEN	Beginn des Symptoms mm–dd–yy Ende des Symtoms mm–dd–yy Wie lange dauerte es? Tage ? Besteht das Symptom immer noch? ☐ JA AUSWIRKUNG DES SYMTOMS Hatte das symtom direkte medizinische Auswirkungen, wie	☐ Nichts ☐ Konsultierte einen Arzt ☐ Stoppte die medikamenten Einnahme Reduzierte die medikamenten Dosis auf ☐ Wechselte das Medikament auf Half es? ☐ JA ☐ Nahm das Medikament wieder und der Effekt erschien wieder

FIG. 16C

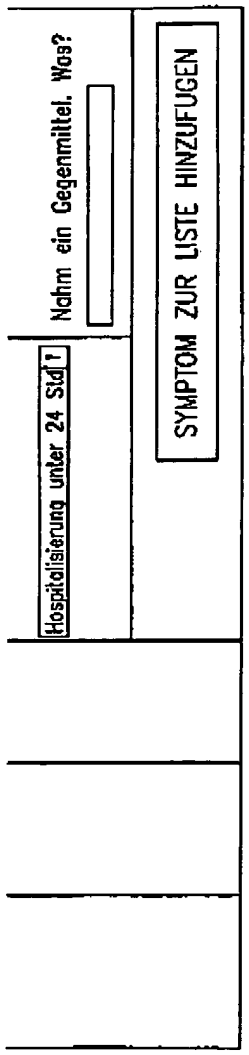


FIG. 16d

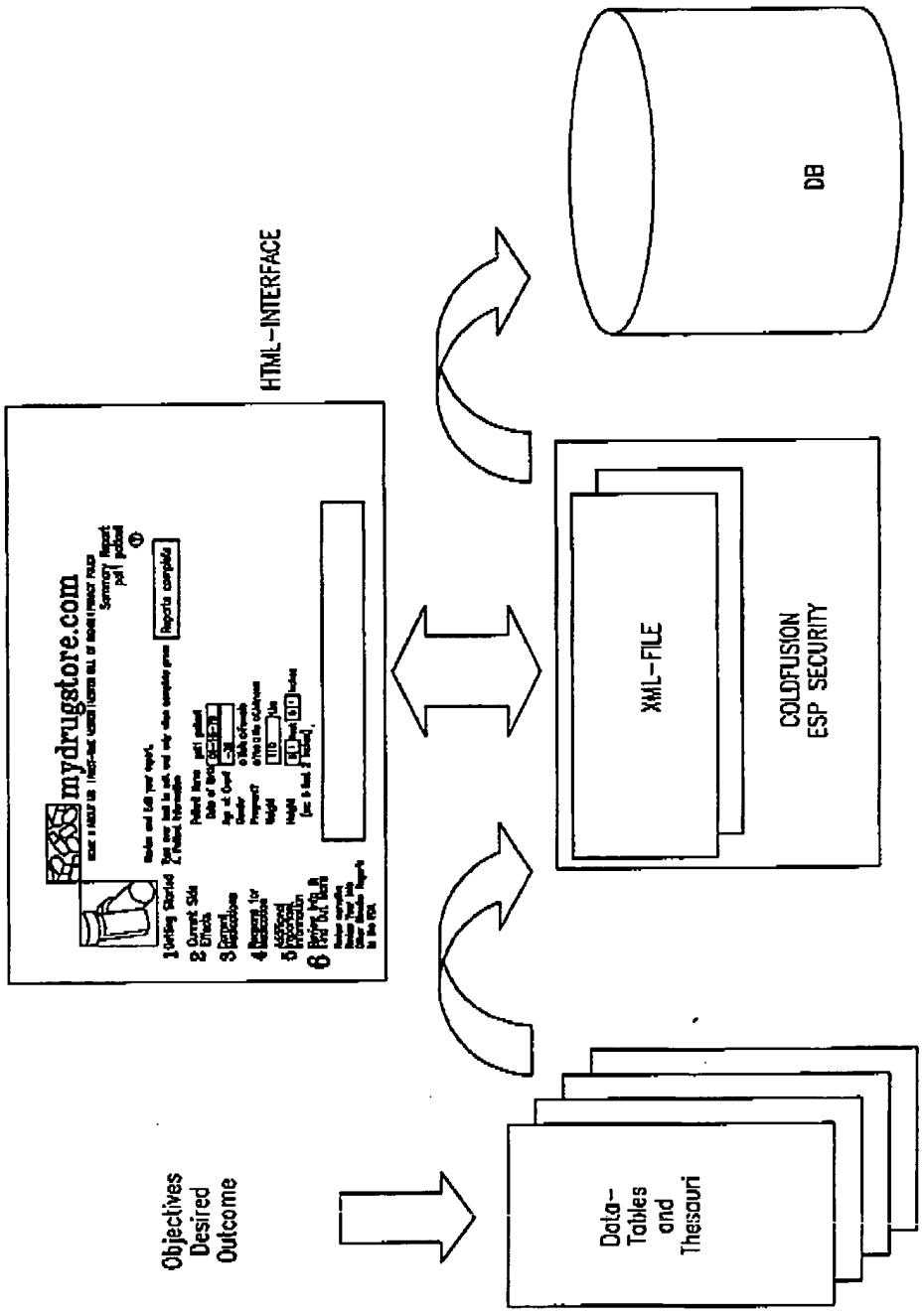


FIG. 17

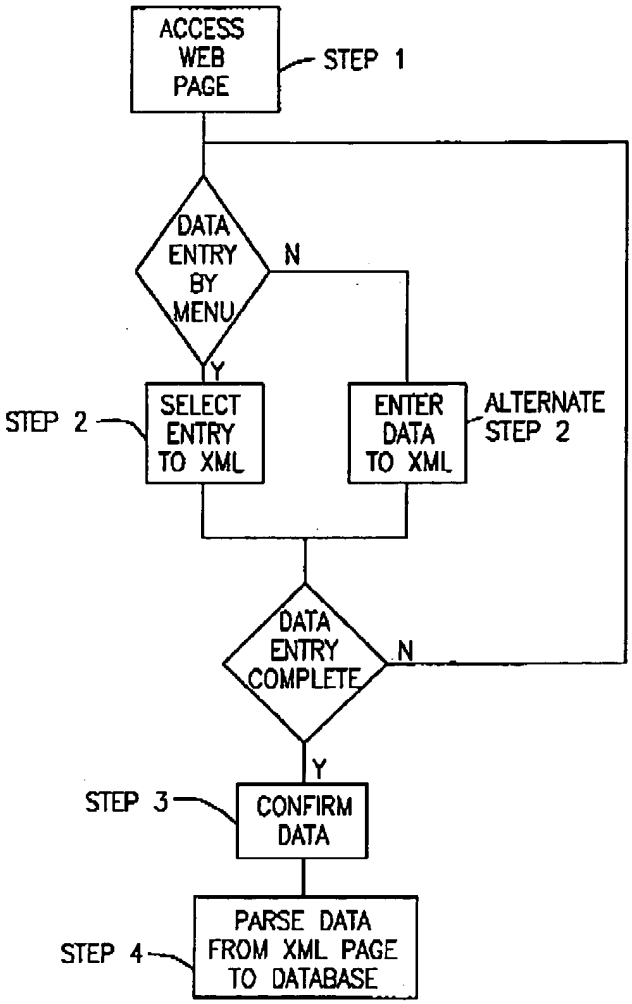


FIG. 18